Please type a plus sign (+) inside this box

Substitute for form 1449A/PTO

PTO/SB/08A (08-00)

TRADEMA are required Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet of

| Complete if Known | | | |
|------------------------|-----------------------|--|--|
| Application Number | 08/462,703 | | |
| Filing Date | June 5, 1995 | | |
| First Named Inventor | Gary D. HODGEN et al. | | |
| Group Art Unit | 1617 | | |
| Examiner Name | E. Webman | | |
| Attorney Docket Number | SCH-1309 C3 | | |

| | | | U.S. PATENT DOCUM | MENTS | | |
|------------------------|--------------|--|-------------------------------|--|--|--------|
| | | U.S. Patent Document | Name of Patentee or Applicant | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant | |
| Examiner Initials * | Cite No.1 | Number Kind Code ² (if known) | | | Passages or Relevant Figures Appear | |
| | | 4,780,461 | Neef et al. | 10/25/1988 | | |
| - 7 - | | | | | | |
| | | | | | Dr. | |
| | <u> </u> | | | | "IECE | IVED |
| | | | | | DC+ | VED |
| | | | | | TFOU OF | 2000 |
| | | - | | | IECH CENT | UU2 |
| | | | | | CENTER 16 | Ya |
| | | | | | 108 | V/2900 |
| | | | | | | |
| | | | | | | 1 |
| | | | | | | |
| | - | | | | | |
| | | | | | | 1 |
| | | | | | | J |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|--------------------------|-------------------------|-----------|--|---|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | For Office ³ | | ment ind Code ⁵ if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Т ₆ |
| 1/2 | | EP | 0 253 607 | Α | | 01/20/1988 | | |
| 01 | | EP | 0 129 499 | Α | | 12/27/1984 | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

| | | | |
|-----------------------|--------------------|------|--|
| Examiner Signature | Date Considered | 4/83 | |

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark hee if English language Translation is attached.



OCT 2 5 2002

TECH CENTER 1600/2900

PTO/SB/08A (08-00) = Approved for use through 10/31/2002, OMB 0651-0031

PADEMARY U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known 08/462,703 Application Number **INFORMATION DISCLOSURE** Filing Date June 5, 1995 STATEMENT BY APPLICANT First Named Inventor Gary D. HODGEN et al. **Group Art Unit** 1617 (use as many sheets as necessary) **Examiner Name** E. Webman Sheet 2 of 2 Attorney Docket Number SCH-1309 C3

| | | OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS | |
|------------------------|--------------|--|----|
| Examiner Initials * | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| 2 | | D. HEALY et al.," Induction of Menses by Antiprogesterone Steroid (RU 486) in Primates: Site of Action, Dose-Response Relationships, and Hormonal Effects," FERTILITY AND STERILITY, Vol. 40, No. 2, 1983, pp. 253-257, XP008002911 | |
| g^{l} | | C.F. CHILLIK et al., "RU486-Induced Menses in Cynomolgus Monkeys: Uniformity of Endometrial Sloughing," FERTILITY AND STERILITY, Vol. 45, No. 5, May 1986, pp. 708-712, XP001068224. | |
| | | H.B. CROXATTO et al., "Late Luteal Phase Administration of RU486 For Three Successive Cycles Does Not Disrupt Bleeding Patterns or Ovulation," JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 65, December 1, 1987, pp. 1272-1277, XP008002486. | |
| | | B. SHORTLE et al., "Effects Of An Antiprogesterone Agent, RU-486, On the Menstrual Cycle of the Rhesus Monkey," JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 60, No. 4, April 1985, pp. 731-735, XP001068228. | |
| | | V.G. GARZO et al., " Effects of An Antiprogesterone (RU486) on the Hypothalamic-Hypophyseal-Ovarian- Endometrial Axis During the Luteal Phase of the Menstrual Cycle," JOURNAL OF ENDOCRINOLOGY AND METABOLISM, Vol. 66, No. 3, 1998, pp. 508-517, XP008002478. | |
| | | L.K. NIEMAN et al., "Use of Single Doses of the Antiprogesterone Steroid RU 486 for Induction of Menstruation in Normal Women," 1985, PLENUM PRESS, New York & London, XP001076665 in "The Antiprogestin Steroid RU 486 and Human Fertility Control," BAULIEU, E.E., Segal S.J. (eds.) | |
| | | D. PHILIBERT, "RU38486 An Original Multifaceted Antihormone in Vivo," 1984, Walter De Gruyter, Berlin, Germany, XP008002479 in "Adrenal Steroid Antagonism Agarwal MK (ed.) | |
| | | L.K. NIEMAN et al., "The Progesterone Antagonist RU 486," THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 316, No. 4, January 22, 1987, pp. 187-191, XP000564124. | |
| | | D. SHOUPE et al., "Effects of the Antiprogesterone RU 486 In Normal Women," AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY, Vol. 157, December 1987, pp. 1415-1420, XP008002485. | |
| | | H.P. ZAHRADNIK et al., "Antigestagene-Grundlagen und Klinik," ARCHIVES OF GYNECOLOGY AND OBSTETRICS, Vol. 250, No. 1, 191, pp. 861-868, XP008002752. | |
| | | E. E. BAULIEU et al., "Antiprogesterone Activity of RU 486 And Its Contragestive And Other Applications," HUMAN REPRODUCTION, Vol. 1, No. 2, 1986, pp. 107-110, XP000564113. | |
| 1 | | K. PARFITT (Ed.) "Martindale – The Complete Drug Reference, 32rd edition," 1999, PHARMACEUTICAL PRESS, LONDON, XP002198132. | |
| J | | | |
| | | | |

| | | | | , |
|---|-----------------------|--------|--------------------|------|
| | Examiner Signature | \sim | Date Considered | 4/03 |
| L | Signature | | Considered | () |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.